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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,404	03/31/2004	Samuel Achilefu	MRD-54DV (1515.1 US)	5388
27805	7590	01/17/2008		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			01/17/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/814,404	Applicant(s) ACHILEFU ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-14, 16, 17, 19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 19 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/30/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1,4-14,16,17,19 and 23 are pending in the application. Claims 4-14 and 16 are withdrawn from consideration. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

### ***Response to Arguments***

1. Applicant's arguments filed 9/25/07 have been fully considered but they are not persuasive.

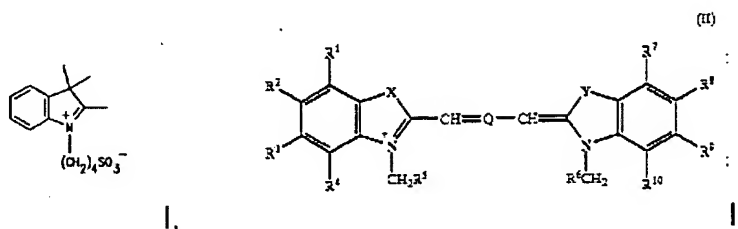
### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al. (WO98/47538 as translated in US 6,534,041B1) as stated in the office action mailed 5/25/07.
4. Applicant amended the instant claim 1 to remove the limitations polyalkoxyalkyl and aminoalkyl.
5. The reference of Licha et al. does disclose that the R<sup>5</sup> of the composition of formula II (below) may be a C<sub>1-50</sub> alkyl chain interrupted by 0 to 15 oxygen atoms and/or 0 to 3 carbonyl groups and/or is substituted with 0 to 5 hydroxy groups, etc. (column 3,

lines 25-30 and 44-50; column 11, lines 36-53), which encompasses the  $Y_1 = -CH_2-(CH_2-O-CH_2)_c-CH_2-OH$  of the instant claims.



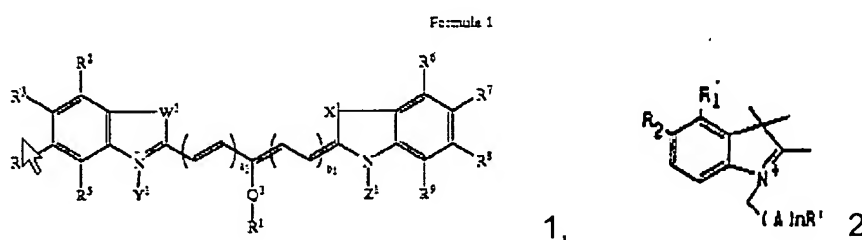
6. It would have been obvious at the time of the invention that the intermediate of formula I (2,3,3-trimethyl-4,5-benzo-3H-indolene) necessarily contains the same  $R^5$  substituent, i.e.  $-CH_2-(CH_2-O-CH_2)_c-CH_2-OH$  in place of the  $C_{1-4}$  sulfoalkyl chain (formula I) in order to generate the composition of formula II as the final product. The resulting  $-CH_2-(CH_2-O-CH_2)_c-CH_2-OH$ , etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Licha et al. encompass the compositions of the instant claims, i.e.  $-CH_2-(CH_2-O-CH_2)_c-CH_2-OH$  substituted.

7. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Achilefu et al. (US 6,180,085B1) as stated in the office action mailed 5/25/07.

8. Applicant amended the instant claim 1 to remove the limitations polyalkoxyalkyl and aminoalkyl.

9.  $Y^1$  of the composition of formula 1 may be  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. (column 2, lines 63) which encompass the substituents of the instant claims. It would have been obvious at the time of the invention that the intermediate of formula 2 (2,3,3-

trimethyl-4,5-benzo-3H-indolene) must be substituted with the same  $Y^1$ , such as  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. in place of the  $(A)_nR$  group (formula 2) in order to generate the final compositions of formula 1. The  $-(CH_2)_9-N(R^{14})-(CH_2)_h-CO_2H$ , etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Achilefu et al. encompass the compositions of the instant claims.



### Conclusion

No claims are allowed at this time.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
January 10, 2008



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER